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(HL)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/186,775 11/06/98 BURGESS D 012176-00621

020350 HM12/0607
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EXAMINER

ZAGHMOUT, O

ART UNIT PAPER NUMBER

1649

DATE MAILED:

06/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/186,775	Applicant(s) Burgess
	Examiner Ousama Zaghmout	Group Art Unit 1649

Responsive to communication(s) filed on Nov 4, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-27 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED OFFICE ACTION

Claims 1-27 are pending.

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Ist Paragraph

Claims 1, 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a plant containing a plant cell comprising a first and a second expression cassette located at the same locus on each of two homologous chromosomes wherein the recombinase in the first expression cassette is present between the first promoter and the first polynucleotide sequence, and the second intervening expression cassette is flanked by two recombinase sites and situated between the first promoter and the first polynucleotide

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sequence. Claims are further directed to a method for modifying cellular function in a plant using said first and second expression cassettes wherein the presence of the first and second polypeptides from inserted genes in a cell is lethal to the cell. However, Applicants have not disclosed a transgenic plant that is transformed by said expression constructs where inserted genes can be transcribed under any promoter. If genes used in these expression constructs were to be driven under a constitutively expressing promoter, it means both genes are expressed and transgenic plants will not be produced. In addition, if these genes were to be driven by tissue specific promoters, there is a likelihood that promoters in both expression cassettes will be expressed in the same tissue at the same time where transgenic plants will not be produced. If an inducible promoters were to be used, they might not be induced in the same manner and under the same conditions and as such no transgenic plants will be produced. Accordingly, one of skill in the art would not have recognized the Applicants to have been in possession of transgenic plants obtained by the claimed methods. Therefore, these claims are rejected under 35 U.S.C. 112, first paragraph for failing to comply with the description of the invention requirement.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are broadly drawn to a plant containing a plant cell comprising a first and a second expression cassette located at the same locus on each of two homologous chromosomes wherein the recombinase in the first expression cassette is present between the first promoter and the first polynucleotide sequence, and the second intervening expression cassette is flanked by two recombinase sites and situated between the first promoter and the first polynucleotide sequence. Claims are further directed to a method for modifying cellular function in a plant using said first and second expression cassettes wherein the presence of the first and second polypeptides from inserted genes in a cell is lethal to the cell. However, Applicants have not disclosed a transgenic plant that is transformed by said expression constructs where inserted genes can be transcribed under any promoter. If genes used in these expression constructs were to be driven under a constitutively expressing promoter, it means both genes are expressed and transgenic plants will not be produced. In addition, if these genes were to be driven by tissue specific promoters, there is a likelihood that promoters in both expression cassettes will be expressed in the same tissue at the same time where transgenic plants will not be produced. If an inducible promoters were to be used, they might not be induced in the same manner and under the same conditions and as such no transgenic plants will be produced.

Moreover, the reduction to practice of a transgenic plant that express genes of the first and the second expression cassettes is essential to determine that the claimed method is enabled as a method of modulating cellular functions in a plant. This is because many

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functions in the plants are controlled by more than 2 genes such as genes which control photosynthesis, germination and respiration. Furthermore, the expression of a transgene does not depend only on the integration into the host genome, said transgene has to be activated which is then has to go through a number of steps such as the initiation of transcription, transcript process, transport to cytoplasm and translation of mRNA. Therefore, it is unpredictable if genes of the first and the second expression constructs will be expressed as expected once they are integrated into the host genome. Applicants have failed to address many of these important issues which are essential for the enablement of the invention as claimed in the instant application. The specification is silent as to the criteria used to identify the nucleotide sequences which encodes transactivating proteins, or transgenic plants that express desired traits. Applicants have not shown the likelihood of producing proteins such as ribonuclease, AVR9 and CF9 which are lethal to a plant cell or contains an ability to modify the cellular functions of a cell. Applicants have provided no specific guidance as to how to select the nucleotide sequences which will produce a protein or a polypeptide conferring the desired effect. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not. Hence, due to the lack of any working examples of the inventions, and the inability of one skilled in the art to predict which if any of all possible proteins will be useful in the manner suggested, and the unpredictability of the field, it would require undue experimentation to practice the claimed invention.

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In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations.

Conclusion

No claims are allowed.

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Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

June 3, 1999


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER